PATENT
Atty. Docket No.: 13024/35946

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	I hereby certify that this paper is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on this date:
McMichael, J. *et al.*	
Serial No.: 09/495,186	
Filed: February 1, 2000	
For: TREATMENT OF SYMPTOMS OF ASTHMA, ALLERGIES AND OTITIS MEDIA	April 18, 2001
Group Art Unit: 1633	Jeffrey S. Sharp Registration No. 31,879
Examiner: Wilson, M.	Attorney for Applicants

DECLARATION OF JOHN McMICHAEL Ph.D. UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

1. I, John McMichael, declare that I am a co-inventor of the subject matter described and claimed in the above-identified patent application. That I received my B.S. in Microbiology from The University of Maine in 1971 and my Ph.D. in Immunology/Virology from Oregon State University in 1973 and that I have practiced in the field of biomedical research for 30 years. I am currently the Chief Operating Officer of Milkhaus Laboratories, Inc. the assignee of the above-identified patent application.

2. I submit this declaration to address issues raised in the Office Action dated October 18, 2000 in the above-identified application. In response to questions presented about the Examples, "preexposure" in Example XXX, refers to preexposure to allergen, which was

heavy air in that Example. Further, each of Examples XXXI, XXXII and XXXIII were not prophetic but reflected work actually conducted.

3. In response to the questions presented about the symptoms treated in Examples XXXIV and XXXV, I confirm that the subjects of those examples suffered from constriction of airways characteristic of asthma with consequent negative impact on their ability to carry out activities of daily life. Practice of the method of the invention on those subjects was successful in alleviating the constriction of airways of those two subjects in a manner which allowed them to engage in carrying out the activities of daily life. Further, the treatment resolved the respiratory symptoms of the subjects in a manner which was unaccompanied by a productive cough.

4. Further, other work has been carried out which shows the ability of the invention to treat the symptoms of Chronic Obstructive Pulmonary Disease (COPD) which is not associated with increased mucous production. Some, but not all, of this work is reported in the above-identified application at Examples XIV, XV, XVI and XVIII. This work supports Applicants' position that the application is enabling for effective treatment conditions not associated with increased mucous production.

5. I also submit this Declaration to state facts relating to the disclosure of methods of treating dyspnea symptoms of respiratory distress in my U.S. Patent No. 6,100,244 ("the '244 Patent) and the disclosure of and claims to methods of treating the symptoms of asthma in the present application. Specifically, I declare that I am the sole inventor of the subject matter directed to treating of asthma symptoms in claims 8-14 of the present application and that any invention relating to treatment of asthma symptoms disclosed but not claimed in the '244 Patent was derived from me.

6. I submit this Declaration to state facts relating to the disclosure of methods of treating the symptoms of otitis media in U.S. Patent No. 5,948,768 Patent ("the '768 Patent") and the disclosure of and claims to methods of treating symptoms of otitis media in the present application. Specifically, I declare that Michael Allen and I were the co-inventors of the subject

matter directed to treating otitis media by administration of ear drops in claims 15-20 of the present application and that any invention relating to the treatment of otitis media by administration of ear drops in the '768 Patent was derived from Michael Allen and me.

7. I am aware that Vernon Durie V.D.M. and Harry C. Gurney D.V.M. are submitting declarations in the above-identified application relating to animal experiments which they conducted with the formulations of the invention. I confirm that compositions which they were supplied with identified as SCTF comprised 0.003 mg/mL (0.0006 mg per 0.2 mL dosage) of DNA derived from salmon testicle or bovine sources.

8. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified interference or any patent issuing thereon.

John McMichael Ph.D.

April 13, 2001